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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 210,031	12 11 1998	ATILAT LORINCZ	2629-4005US1	6182

MORGAN & FINNEGAN
345 PARK AVENUE
NEW YORK, NY 10154

EXAMINER

BRUSCA, JOHN S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/11/2002

31

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/210,031

Applicant(s)

TANG ET AL.

Examiner

John S. Brusca

Art Unit

1631

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED**FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.**

Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 25 June 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ they raise the issue of new matter (see Note below);
(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): The objection to claims 36-54.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☒ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

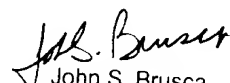
Claim(s) allowed: none.Claim(s) objected to: none.Claim(s) rejected: 36-74.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.

10. ☐ Other: _____


John S. Brusca
Primary Examiner
Art Unit: 1631

Continuation of 5. does NOT place the application in condition for allowance because: The declaration under 37 CFR 1.132 by Atilla T. Lorincz has been considered although the applicants have failed to provide reasons why the declaration was not earlier presented as required under 37 CFR 1.195. The declaration employs an assay of nucleic acids by use of an antibody assay specific for RNA-DNA hybrids. The claimed subject matter is not limited to this assay and other forms of assay, such as direct hybridization of a labeled nucleic acid probe would be expected to work in the cited prior art media absent evidence to the contrary. It is further noted that the assay utilized in the declaration requires stability of RNA for either the assay of RNA or the assay of DNA since it is the RNA-DNA hybrid formed in each assay that is detected by antibodies specific for RNA-DNA hybrids. Other assays of DNA and protein are known in the prior art that do not require stability of RNA in the assay.

Regarding the arguments concerning Harrison and Wainwright references, the arguments concern each reference individually rather than the combination of the references and so do not effectively rebut the rejection under 35 U.S.C. 103.

Regarding the declaration, details of the cell lysis procedure, and the mechanism of detection of the RNA-DNA hybrids are omitted from the declaration. There is not discussion of what step of the procedure the samples were stored for the time points discussed in the declaration. Tables 1 and 2 show similar levels of detection of DNA at week 0 for all media tested and therefore suggest that the Dunphy media meet the limitations of the claimed invention. A significant signal was also obtained using Dunphy media at week 3. Tables 3 and 4 show reduced but still significant levels of detection at day 0 for RNA for the Dunphy media, with a greater reduction of signal at later time than seen in the DNA assay using Dunphy media. It is noted that the claims are not limited to media for detection of RNA, nor are the claims limited to the length of time samples are stored in the media before assay. The declaration states that EDTA does not inhibit ribonucleases, but appears to concede that EDTA would inhibit some DNA nucleases. The motivation for addition of EDTA is that of Dunphy as discussed in the Office action mailed 23 October 2001, namely for a bacteriostatic effect.

The declaration is further unpersuasive because the tested media of Dunphy labeled Dunphy 2 comprises greater than the upper limit of ethanol of 25% suggested by Dunphy, and so use of Dunphy 2 media is contrary to the teachings of Dunphy. All of the Dunphy tested in the declaration fail to include EDTA which would be obvious over Dunphy and is required by the claimed subject matter. The specification states on page 9 that a preferred anti-degradation agent (required by the claimed subject matter) is a chelator and that a preferred chelator is EDTA. Therefore the Dunphy media of the declaration does not test the claimed media that is obvious over Dunphy. The UCM media used in the declaration does not comprise a cross linking agent as required by the claimed subject matter. Therefore the declaration does not effectively show that media taught by Dunphy is less effective than the claimed media.